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PCT/KR2003/002860

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Artcle 36 and Rule 70)

Applicant's or agent's file reference E03-006	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. **PCT/KR2003/002860**	International filing date *(day/month/year)* **27 DECEMBER 2003 (27.12.2003)**	Priority date *(day/month/year)* 27 DECEMBER 2002 (27.12.2002)

International Patent Classification (IPC) or national classification and IPC

IPC7 C07K 16/18, C07K 16/34

Applicant

NEOBIODIGM CO., LTD et al

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demamd	Date of completion of this report
27 JULY 2004 (27.07.2004)	24 MARCH 2005 (24.03.2005)

Name and mailing address of the IPEA/KR
Korean Intellectual Property Office
920 Dunsan-dong, Seo-gu, Daejeon 302-701,
Republic of Korea
Facsimile No. 82-42-472-7140

Authorized officer
PARK, JEONG UNG
Telephone No. 82-42-481-8159

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International aplication No.
PCT/KR2003/002860

I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed

☐ the description:
pages _____ , as originally filed
pages _____ , filed with the demand
pages _____ , filed with the letter of _____

☐ the claims:
pages _____ , as originally filed
pages _____ , as amended (together with any statment) under Article 19
pages _____ , filed with the demand
pages _____ , filed with the letter of _____

☐ the drawings:
pages _____ , as originally filed
pages _____ , filed with the demand
pages _____ , filed with the letter of _____

☐ the sequence listing part of the description:
pages _____ , as originally filed
pages _____ , filed with the demand
pages _____ , filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language English which is

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☒ the language of publication of the international application(under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination(under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide** and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained inthe international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disc losure in the international applicationas as filed has been furinshed.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets _____

5.

☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box(Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed." and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.*

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 6-8

because:

☒ the said international application, or the said claims Nos. 6-8 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

Claims 6-8 relate to diagnostic methods of the human or animal body and according to Art. 34(4)(a)(i) and Rule 67.1(iv) PCT, the IPEA is not required to carry out an international preliminary examination on this claims.

☐ thedescription, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-5, 9-20	YES
	Claims		NO
Inventive step (IS)	Claims	9-18	YES
	Claims	1-5, 19, 20	NO
Industrial applicability (IA)	Claims	1-5, 9-20	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The present invention relates to a monoclonal antibody against asialo alpha1-acid glycoprotein; a method for diagnosing a liver disease which evaluates asialo alpha1-acid glycoprotein in a test sample by using said monoclonal antibody; and an diagnostic strip for immunochromatography composed of said monoclonal antibody against asialo alpha1-acid glycoprotein and Ricinus communis agglutinin (RCA).

The following documents have been considered for the purpose of this report:
D1: EP 0199196 A2 (KURARAY CO., LTD.) 29 October 1986
D2: WO 2001/035105 A1 (KRIBB & KOBIAS CO., LTD.) 17 May 2001

1. Novelty

D1 relates to a monoclonal antibody specific for an alpha-acid glycoprotein or specific for at least one antigenic determinant included in a sugar chain of the following formula which is contained in glycoproteins such as alpha1-acid glycoprotein. D2 discloses a method and a kit for measuring the concentration of asialo-glycoprotein by using lectin recognizing asialo-glycoprotein as at least one of a capture protein or a probe protein through a sandwich assay to measure the concentration of asialo-glycoprotein being present excessively in the blood when developing from normal into hepatitis, liver cirrhosis, or hepatocellular carcinoma. However, the use of a monoclonal antibody binding only with asialo alpha1-acid glycoprotein excluding heptoglobin and alpha2-macroglobulin is not disclosed in any of the prior art. Therefore, the subject-matter of claims 1-5, 9-20 is considered to be novel under PCT Article 33(2).

2. Inventive Step

In comparison with D1 and D2, the present invention claimed in claims 1-5, 19, 20 shows a difference in the use hybridoma cell line which can produce in a large scale a monoclonal antibody binding only with asialo alpha1-acid glycoprotein excluding heptoglobin and alpha2-macroglobulin. However, the present invention claimed in claims 1-5, 19, 20 is considered to be easily invented by a person skilled in the art with knowledge of the prior art documents D1 and D2, without the exercise of inventive skill. Therefore, the subject-matter of claims 1-5, 19, 20 is not considered to involve an inventive step under PCT Article 33(3). The prior art document does not teach or suggest the use of an diagnostic strip for immunochromatography claimed in claims 9-18 which comprises a monoclonal antibody reacting only with asialo alpha1-acid glycoprotein excluding heptoglobin and alpha2-macroglobulin. Therefore, the subject-matter of claims 9-18 is considered to involve an inventive step under PCT Article 33(3).

3. Industrial Applicability

The subject-matter of claims 1-5, 9-20 is considered to be industrially applicable under PCT Article 33(4).